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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,063	08/08/2001	Scott C. Barnes	17644-66	2615

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EXAMINER

JOYNES, ROBERT M

ART UNIT PAPER NUMBER

1615

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/925,063	Applicant(s) BARNES ET AL.	
	Examiner Robert M. Joynes	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-66 is/are pending in the application.
- 4a) Of the above claim(s) 1-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicants' Amendment filed on December 24, 2003.

Claim Rejections - 35 USC § 112

Claims 21, 43-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner is seeking clarification in how these claims differ from each other. Claims 21 and 43 appear to be duplicate claims. Claim 21 recites a top roll, center roll and lower roll. Claim 43 recites a first roll, second roll, and third roll. The Examiner seeks clarification as to how these are different, if they are in fact different. It appears that the rolls are the same.

As for Claims 44 and 45, the only difference between the two claims is the word "then" included before the word calendering is step e. It would appear that these claims are duplicate claims but clarification is requested as to any difference between the claims.

Claim 45 also recites that the adhesive layer is formed and adhered to the backing layer in one single manufacturing step. Yet, the claims recites that the blend is extruded and THEN calendered. This would appear to be at least two manufacturing steps, not one step. Additional clarification is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 21-28, 32-40, 42-52, 56-64, 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cilento et al. in combination with Sablotsky et al. (US 4994278). Cilento teaches an adhesive dressing for use on human skin (Col. 4, lines 8-23). The adhesive layer of the dressing comprises a polyisobutylene component (Col. 4, lines 24-34), styrene copolymers (Col. 4, lines 35-51), water-soluble agents such as hydrocolloid gums (Col. 4, line 52 – Col. 5, line 13) as well as mineral oil, tackifiers and antioxidants (Col. 5, lines 14-37). The dressing further comprises a backing film (Col. 5, line 52 – Col. 6, line 7). An active agent is incorporated into the adhesive layer (Col. 6, lines 8-41). The layers can be form through calendaring (Col. 7, lines 10-38). The adhesive layer is from about 20 to about 100 millimeters (Col. 5, lines 38-42) and the polymeric backing layer is from about 1 to 5 millimeters (Col. 6, lines 3-5).

Cilento does not expressly teach that the backing layer comprises ethylene acrylic acrylate or ethylene butyl acrylate or ethylene ethyl acrylate or ethylene methyl acrylate or the specific monomer concentrations recited in Claim 1.

Sablotsky teaches that a backing layer for transdermal compositions can be ethylene methyl acrylate (Col. 7, lines 10-18) and that ethylene ethyl acrylate is a known polymers used for films (Col. 2, lines 1-51)

Neither Cilento nor Sablotsky teach the exact concentration ranges of the polymeric backing layer.

While the reference does not teach the complete concentration ranges, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to use any known polymeric component(s) for the backing layer of a transdermal composition and to adjust the concentrations of the ingredient and to adjust the thickness of the individual layers. No criticality is seen in the particular monomeric concentration ranges. The polymers are known in the art as films but no unexpected results are seen from the particular monomeric concentrations.

One of ordinary skill in the art would have been motivated to do this to increase or decrease the barrier properties of the backing layer. The amount and type of active agent would dictate the additional ingredients necessary and the amounts of each ingredient. Thickness is also determined by one of ordinary skill in the art depending on the active agent used and the material used to form the layers.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 29-31, 41 and 53-55, 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cilento et al. in combination with Sablotsky et al. in further combination with Godbey et al. (US 5372819). The teachings of Cilento and Sablotsky are discussed above. Neither Cilento nor Sablotsky teach that the polymeric backing layer further comprises additional additives.

Godbey teaches a transdermal delivery system in which the backing layer can contain polymer additives such as processing aids, pigments, and lubricants (Col. 4, lines 30-36).

While the reference does not teach the complete concentration ranges, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to include additives in the polymeric backing layer of a transdermal composition.

One of ordinary skill in the art would have been motivated to do this to change the color of the composition or to change the flexibility of the backing layer.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicants' arguments filed on December 24, 2003 have been considered but are not found to be persuasive. Applicants argue that the prior art fails to teach or suggest a hydrocolloid dressing that is manufactured by calendering the adhesive layer and backing layer simultaneously to form the dressing as well as a backing layer that has the recited monomeric concentrations for the copolymer.

With regard to the method claims, it is the position of the Examiner that no criticality is seen in reducing the number of steps in the preparation of the dressing. While the Examiner recognizes and appreciates the new language of the claim, the end product is the same and no unexpected results are seen from calendering the adhesive directly to the backing film. It is not understood what advantages the removal of this step has on the process or the product. While, the applicants recited that economic advantages are achieved or efficiency in the manufacturing is achieved, it is unclear how or to what extent these advantages are realized. Therefore, the rejections over the cited prior art are maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

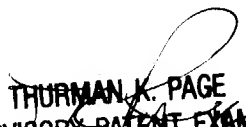
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Joyner whose telephone number is (571) 272-0597. The examiner can normally be reached on Mon.-Thurs. 8:30 - 6:00, alternate Fri. 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert M. Joynes
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Art Unit 1615


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